PO BOX 5606 BELLINGHAM, WA 98227

www.nongmoproject.org | +1.360.255.7704

February 26, 2021

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Food Safety and Inspection Service

Docket No.: APHIS-2020-0079

RE: Comments on proposed regulation of the movement of animals modified or developed by genetic engineering

The Non-GMO Project values the opportunity to comment on the establishment of regulations for the movement of certain animals modified or developed by genetic engineering. We appreciate the complexity of this consideration and we sincerely hope our unique expertise can be of service in determining the course of action that best maintains the utmost rigor and transparency from this regulatory framework.

The Non-GMO Project currently offers North America's most rigorous and recognized program for Genetically Modified Organism (GMO) avoidance. Our mission is to preserve and build the non-GMO food supply, educate consumers, and provide verified non-GMO choices.

More than any other group or non-governmental organization in the country, we understand the public's expectations regarding GMOs and their transparency. As a nonprofit organization that currently verifies more than 60,000 products for GMO avoidance, we represent thousands of companies and millions of consumers who together comprise a nearly $40 billion industry -- an industry that's grown 15% in the last year alone and now commands upwards of 9% of the overall food industry.

Our exceptional understanding of the public's opinions on GMOs is informed by our technical work with industry supply chains and our robust communications with the more than 1.2 million followers of our social media accounts. It's also informed by independent consumer research. In 2020, an extensive study by Hartman Group offered clear and compelling data: "Consumers continue to demand transparency about GMOs as they become aware of newer biotechnology like gene editing." [1]

As creators of the United States' most well-established certification standard for GMO avoidance, we know firsthand from a technical standpoint what is required to provide GMO transparency. Genetic engineering and GMOs are scientifically complex. That complexity demands not only a factually sound, universal definition of genetic engineering, but also rigorous oversight of the biotechnology industry, where arcane techniques can easily slip past all but the sharpest scrutiny.

[1] Organic & Beyond © 2020 The Hartman Group, Inc.

The Non-GMO Project Standard defines GMOs in accordance with the most authoritative international definition of GMOs, the *Codex Alimentarius*. The complexity of our standard and our robust testing - and process-based program reveal the scientific and technical rigor it takes to evaluate products and supply chains for GMO presence.

Our deep understanding of the public's desire for GMO transparency combined with our industry expertise gives us grave concerns about any change in regulation of genetically engineered animals that could reduce rigor. Below we strive to offer clear and informed reasons for our position.

1. Regulation must be designed and conducted with the utmost rigor

The genetic manipulation of animals is a scientific endeavor that's extremely complex. Its esoteric techniques introduce vast amounts of variables and implications for people, animals and the environment--many of which are still unknown due to lack of long-term testing and independent research.

The regulatory framework for genetically engineered animals must be sufficiently and thoroughly rigorous. It is imperative that the safety of the animal and the safety of those who consume that animal are ensured through ironclad policy and scrupulous oversight.

No company modifying or engineering the genetic material of animals should be allowed to self-determine whether their products qualify for exemptions from regulation. Moreover, all company efficacy claims should pass regulatory approval, and environmental impacts must be adequately reviewed. Relaxed regulatory oversight only introduces unnecessary and unknown new risks.

2. The regulatory framework must adhere to public demand for GMO transparency

The public expects that if genetic engineering has been used in the development of an animal, then the resulting product is a GMO. It is the technique, not the outcome, that makes an organism genetically engineered or modified in the public's mind. Under this assessment, these genetically engineered animals and their derivatives introduce GMOs at entry points in the supply chain.

In 2007, the Non-GMO Project Standard was developed to answer the public's call for GMO transparency — not just in final products but through the entire supply chain. Our voluntary consensus Standard has been developed over time by input from the public, including supply chain members, consumers, and scientists. From its inception, these stakeholders have prohibited the use of genetically modified animals in Non-GMO Project Verified products. The diversity present in the supply chain today gives consumers the opportunity to choose what they purchase based on their preferences and values. The 60,000 products verified to the Non-GMO Project Standard showcase the significant consumer demand for GMO transparency and non-GMO options.

Research conducted in 2020 concludes that 1 in 3 shoppers is more likely to buy non-GMO choices.[2] Of shoppers aware of GMOs:

- 65% believe GMO labeling should be mandatory.[3]
- 40% say they actively try to find out which products contain GMOs.[3]
- Nearly 40% consider GMOs unsafe to eat.[4]

Because the public recognizes the lack of long-term testing on genetically engineered animals and the potential for off-target effects, consumers continue to demand transparency and deserve the right to choose what they're eating. These genetically engineered animals and their derivatives must be identified and labeled at all steps in the supply chain, from input to finished product.

3. The regulation must align its definition of "genetically engineered animal" with international standards and adopt the terms "Biotechnology" and "Genetically Modified Organism"

Under the Non-GMO Project Standard, a Genetically Modified Organism (GMO)[5] is "an organism to which Biotechnology has been applied and derivatives of such an organism; cloned animals are included within this definition." Biotechnology[6] is defined as "the application of:

a. *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or
b. fusion of cells beyond the taxonomic family, that overcame natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection."

This paradigm defines a GMO based on the process used to modify the organism and considers any derivative of the organism, regardless of degree of processing, to be genetically modified (GM). In this way, a non-GMO food ingredient is derived from a non-GMO crop source, non-GMO animal source, and so forth.

A GMO or genetically engineered organism should be defined based on the process used to create it, not the traits present in the final product. All forms of biotechnology including gene-editing techniques, resulting in what is commonly referred to as changes that could be found in nature or developed through conventional breeding methods produce a GMO.

[2] Linkage Research January 2020
[3] Organic & Beyond © 2020 The Hartman Group, Inc.
[4] Pew Research Center, Sept. 2020, "Science and Scientists Held in High Esteem Across Global Publics"
[5] https://www.nongmoproject.org/wp-content/uploads/Non-GMO-Project-Standard-Version-16.pdf
[6] Adapted from Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.

Defining a genetically engineered animal based on the process used to create it, not by the modification present in the animal, is consistent with the Cartagena Protocol on Biosafety,[7] the Codex Alimentarius,[8] and the European Union's GMO Legislation. Failure to harmonize definitions, allowable thresholds for accidental or technically unavoidable GM contamination, and failure to segregate GM animals and their derivatives, could negatively impact international trade by resulting in costly rejected shipments. Alignment with these international agreements, standards, and regulations will facilitate international trade.

4. Responses to Specific Questions Posed by USDA

• **Question:** *Are there types of modifications that should make an animal of an amenable species modified or developed using genetic engineering eligible or ineligible for the expedited safety review process outlined above?*

> All amenable species modified or developed using genetic engineering should be held to the same level of rigorous evaluation for safety of the animal, the safety of anyone who may eat the animal, claim efficacy, and ongoing environmental impact; no expedited reviews should be granted based on the type of modification.

• **Question:** *Should USDA exempt certain types of genetic modifications of amenable species intended for agricultural use from regulation? If so, what types of modifications and why?*

> USDA should base the regulations on the process used to genetically engineer or modify the animal in accordance with international standards and regulations. For this reason, all amenable species should be subject to the same level of rigorous ongoing safety evaluation and environmental impact evaluation and no genetically engineered or modified animals, regardless of the type of genetic modification, should be exempt from regulation.

• **Question:** *What documentation, if any, should accompany amenable species modified or developed using genetic engineering destined for slaughter, certifying that their modifications have been assessed by USDA (APHIS and FSIS)?*

> Documentation supporting segregation and traceability of genetically engineered or modified amenable species should accompany the animals at every step in the supply chain from birth to slaughter. Documentation supporting segregation, traceability, and labeling should accompany all derivatives of genetically engineered or modified animals, regardless of degree of processing, to facilitate transparency in the marketplace, and to respect and support domestic and international specialty markets that may prohibit or require the labeling of the derivatives of genetically engineered or modified animals.

[7] Secretariat of the Convention on Biological Diversity. (2000). Handbook of the Convention on Biological Diversity: Including its Cartagena Protocol on Biosafety. Montreal: Secretariat of the Convention on Biological Diversity.
[8] Joint FAO/WHO Codex Alimentarius Commission. (1992). Codex alimentarius. Rome: Food and Agriculture Organization of the United Nations.

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On behalf of the thousands of brands, food manufacturers, food processors and farmers invested in Non-GMO Project product verification, and the millions of consumers who rely on the Non-GMO Project label for making their GMO avoidance purchasing decisions, we appreciate your giving careful consideration to these uniquely informed comments.

Sincerely,

Megan Westgate
Executive Director
Non-GMO Project